Remarks

The Final Office Action mailed 18 January 2006 has been received and reviewed. Claim 41 having been amended, the pending claims are claims 33-37, 39-45, and 52-54. Reconsideration and withdrawal of the rejections are respectfully requested.

Obviousness-Type Double Patenting Rejection

Claims 33-37, 39-45, and 52-54 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of co-pending Application No. 10/659,571. Further, claims 33-37, 39-45, and 52-54 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of co-pending Application No. 10/936,989. Finally, claims 33-37, 39-45, and 52-54 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of co-pending Application No. 10/937,059. Upon an indication of otherwise allowable subject matter and in the event these rejections are maintained, Applicants will provide an appropriate response.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 33-37, 39-45, and 52-54 under 35 U.S.C. §103(a) as being unpatentable over Komp et al. (U.S. Patent No. 5,098,694) in view of Andrews et al. (U.S. Patent No. 5,460,833), or Andrews et al. (U.S. Patent No. 5,569,461). This rejection is respectfully traversed.

Komp et al. is directed to a deodorant composition. Komp et al. do not teach a desire for total kill of bacteria; rather, they only want to kill odor-causing bacteria. At column 1, lines 31-35, for example, they state that "bacterial agents used in [conventional] deodorants also exhibit undesirable properties because they totally destroy the microbial flora of the skin, disturbing biological equilibrium." Thus, Komp et al. want to maintain a biological equilibrium by only killing odor-causing bacteria. Furthermore, Komp et al. teach a desire to avoid irritation of the

skin. See, e.g., column 3, lines 34-38 where they state "[t]he deodorant of the invention exhibits excellent odor suppression properties... and does not cause the irritation often found with other commercial preparations."

Thus, contrary to the Examiner's assertion at page 5 of the Office Action, a person of ordinary skill would not find it obvious to employ anionic surfactants, for example, as disclosed in Andrews et al. '833, in the compositions of Komp et al. First, Andrews et al. '833 disclose that anionic surfactants in the disclosed compositions are effective against both gram-negative and gram-positive bacteria (e.g., see column 3, lines 36-39). That is, anionic surfactants are capable of a broad spectrum of kill. This is contrary to the properties desired by the Komp et al. deodorant compositions. Also, dioctyl sodium sulfocuccinate and sodium laurylsulfate are irritating to tissue (see, e.g., Exhibits A & B), which is also contrary to the properties desired by the Komp et al. deodorant compositions. Furthermore, Andrews et al. do not teach salicylic acid, benzoic acid, or a combination thereof. Thus, a person of skill in the art would not combine the teachings of Andrews et al. with Komp et al.

Also, the Examiner stated at page 7 of the Office Action that one of ordinary skill would be motivated to prepare a kit based on the compositions of Andrews et al. and Komp et al. Applicants respectfully disagree. There is no teaching or suggestion of stability problems in either document, so there would be no need to consider separating components as a means of solving such problems. Furthermore, one of skill in the art would not be motivated to form a kit without some reason because of the inconvenience and cost associated with separation of the components.

The Examiner rejected claims 33, 35-37, 39, 41-51, and 52-54 under 35 U.S.C. §103(a) as being unpatentable over Beerse et al. (U.S. Patent No. 5,968,539). This rejection is respectfully traversed.

Beerse et al. do not teach or suggest Applicants' invention. It is respectfully submitted that one of skill in the art would not be motivated to select glyceryl laurate, which is one of over

150 compounds listed in columns 4 through 8 of Beerse et al. This is particularly true in view of the fact that glyceryl laurate is not one of the preferred compounds nor is it used in any of the working examples of Beerse et al. Therefore, there is no teaching that would lead one to select such a compound for use in the combination of components selected by Applicants. Furthermore, there is no teaching or suggestion of stability problems in Beerse et al. so there would be no need to consider separating components as a means of solving such problems. Furthermore, one of skill in the art would not be motivated to form a kit without some reason because of the inconvenience and cost associated with separation of the components.

Finally, the Examiner did not accept the Declaration of Matt Scholz as persuasive since it did not provide evidence of "unexpectedly good activity" over the prior art. It is respectfully submitted that unexpected properties do not have to relate to activity. The point of the Declaration was to present unexpected properties with respect to stability. The design of the experiments presented in the Declaration was discussed with the previous Examiner prior to carrying out the experiments. Furthermore, the previous Examiner indicated that such evidence would be considered carefully. Reconsideration is requested.

Summary

It is respectfully submitted that the pending claims 33-37, 39-45, and 52-54 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted
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April 13, 2006
Date

By: Ann M Mueting
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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 13 day of April, 2006, at 6:35 pm (Central Time).

By: MARC IRELAND
Name: MARC IRELAND

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JOURNAL OF THE AMERICAN COLLEGE OF TOXICOLOGY

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Final Report on the Safety Assessment of Sodium Lauryl Sulfate

Sodium Lauryl Sulfate is an anionic surfactant used in cosmetics and industrial chemicals as a cleansing agent. In absorption, metabolism and excretion studies Sodium Lauryl Sulfate had a degenerative effect on the cell membranes because of its protein denaturing properties. High levels of skin penetration may occur at even low use concentration.

Sodium Lauryl Sulfate had an LD 50 (Lethal Dose for 50% of the animals tested) of 0.8 to 110 g/kg in rats. A formulation containing 15% caused depression, labored breathing, diarrhea and death in 4 out of 20 animals.

In acute ocular tests, 10% Sodium Lauryl Sulfate caused corneal damage to the rabbits' eyes if not irrigated or irrigation was delayed. A Draize test of a product containing 5.1% Sodium Lauryl Sulfate caused mild irritation and products containing 21% were severely irritated with no rinse and mildly irritated when rinsed.
Acute animal skin irritation studies of 0.5% to 10% Sodium Lauryl Sulfate cause slight to moderate irritation. Applications of 10% to 30% caused skin corrosion and severe irritation. Solutions above 20% were highly irritating and dangerous. One percent and 5%

Health Information

Natural Health

Glycemic Index

Nutritional supplements

Vitamins & Minerals

Womens health

Cholesterol
- lowering your cholesterol
- High cholesterol diet
- Healthy cholesterol levels

Heart Disease

Diets

Cancers

Omega 3

Hydrogenated fats

Arthritis

Aspartame

Exhibit A

Sodium Lauryl Sulfate produced a significant number of comedones when applied to the pinna of albino rabbits.

A chronic oral feeding study in rats of 0.25%, 0.5% and 1.0% Sodium Lauryl Sulfate in the diet for two years produced no observable abnormalities except for moderate to severe dermal effects. In mutagenesis studies, rats fed 1.13% and 0.56% Sodium Lauryl Sulfate in the diet for 90 days produced no more chromosomal aberrations or clastogenic effects than did a normal diet.

Sodium Lauryl Sulfate was tested for human skin irritation in concentrations ranging from 0.1% to 10%. Open patches were less irritating than closed patches, and irritation increased directly with concentration. For prolonged contact with skin, concentration should not exceed 1%.

CHEMICAL AND PHYSICAL PROPERTIES
Sodium Lauryl Sulfate, an anionic surfactant, is prepared by the sulfation of commercially available lauryl alcohol form coconut our, with either sulfur trioxide or chlorosulfonic acid. The product of the reaction is then neutralized with aqueous sodium hydroxide (lye). The abbreviated symbol for Sodium Lauryl Sulfate is used around the world in clinical studies as a skin irritant. SLS is the universal standard, by which a measured percentage is evaluated to promote a given level of irritation and reaction. By this SLS standard level or irritation, it is then possible to evaluate the healing or modifying characteristics of any ingredient or formula used on the SLS irritated skin.

Carcinogenic nitrates can form in the manufacturing of Sodium Lauryl Sulfate or by its inter reaction with other nitrogen bearing ingredients within a formulation utilizing this ingredient
Tests show permanent eye damage in young animals from skin contact in non eye areas. Studies at Georgia Medical College indicated Sodium Lauryl Sulfate kept young eyes from developing properly by possibly denaturing the proteins and not allowing for proper structural formation. This damage was permanent.

Other studies have indicated that Sodium Lauryl Sulfate enters and maintains residual levels in the heart, the liver, the lungs and the brain from skin contact. This poses question of it being a serious potential health threat to its use in shampoos, cleansers, and tooth pastes.

Still other research has indicated SLS may be damaging to the immune system, especially within the skin. Skin layers may separate and inflame due to its protein denaturing properties.
A higher foaming and slightly less irritating modification of Sodium Lauryl Sulfate can he manufactured by ethoxylation of the surfactant. The modified compound becomes know as Sodium Lauryl Ether Sulfate. The cosmetic name is Sodium Laureth Sulfate with an abbreviated symbol of SLES.

Back from the ACT report on the safety of SLS to Sodium Lauryl Sulphate

Related Links

SLS-free personal and household products
The potential health-effects of SLS
SLS. The killer in your bathroom?

CYTEC

Exhibit B

MSDS: 0001704
Date: 01/18/2006
Supersedes: 08/21/1998

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name:	**COMPLEMIX® 100 Surface Active Agent**
Synonyms:	Dioctyl sodium sulfosuccinate; DSS
Chemical Family:	Ester
Molecular Formula:	C20H37NaO7S
Molecular Weight:	444

CYTEC INDUSTRIES INC., FIVE GARRET MOUNTAIN PLAZA, WEST PATERSON, NEW JERSEY 07424, USA
For Product Information call 1-800/652-6013. Outside the USA and Canada call 1-973/357-3193.
EMERGENCY PHONE: For emergency involving spill, leak, fire, exposure or accident call CHEMTREC: 1-800/424-9300. Outside the USA and Canada call 1-703/527-3887.

2. COMPOSITION/INFORMATION ON INGREDIENTS

OSHA REGULATED COMPONENTS

Component / CAS No.	%	(w/w)	OSHA (PEL):	ACGIH (TLV)	Carcinogen
Sodium dioctyl sulfosuccinate 577-11-7	99.0		Not established	Not established	-

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

APPEARANCE AND ODOR:

Color:	white
Appearance:	solid or rolls of tissue thin wax-like sheets
Odor:	octyl alcohol

STATEMENTS OF HAZARD:
WARNING! CAUSES EYE AND SKIN IRRITATION

POTENTIAL HEALTH EFFECTS

EFFECTS OF EXPOSURE:
The estimated acute oral (rat) LD50, acute dermal (rabbit) LD50 and 4-hour inhalation (rat) LC50 values for this material are 3100 mg/kg, >10000 mg/kg and >20 mg/l, respectively. Direct contact with this material may cause moderate eye and skin irritation. Refer to Section 11 for toxicology information on the regulated components of this product.

4. FIRST AID MEASURES

Ingestion:
If swallowed, call a physician immediately. Only induce vomiting at the instruction of a physician. Never give anything by mouth to an unconscious person.

Skin Contact:
Remove contaminated clothing and shoes without delay. Wash immediately with plenty of water. Do not reuse contaminated clothing without laundering. Get medical attention if pain or irritation persists after washing or if signs and symptoms of overexposure appear.

Eye Contact:
Rinse immediately with plenty of water for at least 15 minutes. Obtain medical advice if there are persistent symptoms.

Inhalation:
Material is not expected to be harmful if inhaled. Remove to fresh air.

5. FIRE-FIGHTING MEASURES

Extinguishing Media:
Use water spray or fog, carbon dioxide or dry chemical.

Protective Equipment:
Firefighters, and others exposed, wear self-contained breathing apparatus. Wear full firefighting protective clothing. See MSDS Section 8 (Exposure Controls/Personal Protection).

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:
Where exposure level is not known, wear approved, positive pressure, self-contained respirator. Where exposure level is known, wear approved respirator suitable for level of exposure. Refer to Section 8 (Exposure Controls/Personal Protection) for appropriate personal protective equipment.

Methods For Cleaning Up:
Sweep up into containers for disposal. Flush spill area with water.

7. HANDLING AND STORAGE

HANDLING

Precautionary Measures: Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Special Handling Statements: None

STORAGE
None

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Measures:
Where this material is not used in a closed system, good enclosure and local exhaust ventilation should be provided to control exposure.

Respiratory Protection:
For operations where inhalation exposure can occur, use an approved respirator recommended by an industrial hygienist after an evaluation of the operation. Where inhalation exposure can not occur, no respiratory protection is required. A full facepiece respirator also provides eye and face protection.

Eye Protection:
Wear eye/face protection such as chemical splash proof goggles or face shield. Eyewash equipment and safety shower should be provided in areas of potential exposure.

Skin Protection:
Avoid skin contact. Wear impermeable gloves and suitable protective clothing.

Additional Advice:
Food, beverages, and tobacco products should not be carried, stored, or consumed where this material is in use. Before eating, drinking, or smoking, wash face and hands thoroughly with soap and water.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color:	white
Appearance:	solid or rolls of tissue thin wax-like sheets
Odor:	octyl alcohol
Boiling Point:	Not applicable
Melting Point:	Not available
Vapor Pressure:	Not applicable
Specific Gravity/Density:	1.1
Vapor Density:	Not applicable
Percent Volatile (% by wt.):	Negligible
pH:	Not applicable
Saturation In Air (% By Vol.):	Not applicable
Evaporation Rate:	Not applicable
Solubility In Water:	1.5g/100 g @ 25 °C
Volatile Organic Content:	Not available
Flash Point:	Not applicable
Flammable Limits (% By Vol):	Not applicable
Autoignition Temperature:	Not available
Decomposition Temperature:	Not available
Partition coefficient (n-octanol/water):	Not available
Odor Threshold:	Not available

10. STABILITY AND REACTIVITY

Stability:	Stable
Conditions To Avoid:	None known
Polymerization:	Will not occur
Conditions To Avoid:	None known
Materials To Avoid:	Strong acid and alkalies cause hydrolysis. Aqueous solutions of this product corrode steel.

Hazardous Decomposition Products: carbon monoxide
carbon dioxide
oxides of sulfur (includes sulfur di and tri oxides)

11. TOXICOLOGICAL INFORMATION

Toxicological information for the product is found under Section 3. HAZARDS IDENTIFICATION.
Toxicological information on the regulated components of this product is as follows:

Sodium dioctyl sulfosuccinate (DSS) has an average oral (rat) LD50 of 3.1 g/kg, based on measured values of 1.9 g/kg, 3.08 g/kg, and 4.3 g/kg. The dermal (rabbit) LD50 is >10 g/kg. DSS has caused moderate skin and eye irritation in animals, to varying extents, depending on the formulation of the tested material (e.g. solid vs. solution), the tested concentration, and the exposure duration. Following 24-hour dermal application (rabbits) of 8 - 10 g/kg solid DSS, the only effect observed was mild erythema. In other rabbit skin irritation tests, the primary irritation score for 100% DSS was ~ 4 and that for 80% DSS with propylene glycol was ~3, both resulting in a moderate irritant classification. Solid DSS applied to the eyes of rabbits produced moderate irritation. Solutions of DSS appear to cause irritation at lower concentrations than the solid material. In rabbits, a concentration of 1% was the lowest reported effective dose necessary to produce slight dermal erythema and at concentrations from 5 - 25% moderate dermal irritation occurred. Mild eye irritation in rabbits occurred following treatment with concentrations between 0.1 and 0.5% DSS. Humans appear to be less sensitive to DSS for skin irritation. In humans, a concentration of 1% was the highest no-effect level observed for skin irritation following a 24-hr patch test. In a modified Draize-Shelanski repeat-insult patch test, DSS showed little evidence of irritation and no evidence of eliciting an allergic response in human subjects. Results from a 90-day subacute oral diet (rat) study indicate a NOEL of 0.94 g/kg/day and results from a 6-month subchronic oral diet (rat) study indicate a LOEL of 0.87 g/kg/day. No indication of significant gross or microscopic adverse effects were reported. Chronic toxicity studies in rats (2-yr) and dogs (1-yr) also reported no significant adverse effects at the doses administered. No adverse effect on reproductive function or fetal development were observed in rats treated with DSS at 0.5 and 1.0% doses, which were not maternally toxic.

12. ECOLOGICAL INFORMATION

This material is not classified as dangerous for the environment.

FISH TEST RESULTS

Test: Acute toxicity, freshwater (OECD 203)
Duration: 96 hr.
Species: Bluegill Sunfish (Lepomis macrochirus)
>37 - 100 mg/l LC50

Test: Acute toxicity, freshwater (OECD 203)
Duration: 96 hr
Species: Rainbow Trout (Oncorhyncus mykiss)
>28 - 100 mg/l LC50

INVERTEBRATE TEST RESULTS

Test: Acute Immobilization (OECD 202)

Duration: 48 hr
Species: Water Flea (Daphnia magna)
>36 - 100 mg/l EC50

DEGRADATION

Test: DOC Die-away (OECD 301A)
Duration: 28 day **Procedure:** Ready biodegradability
>95 %

13. DISPOSAL CONSIDERATIONS

The information on RCRA waste classification and disposal methodology provided below applies only to the Cytec product, as supplied. If the material has been altered or contaminated, or it has exceeded its recommended shelf life, the guidance may be inapplicable. Hazardous waste classification under federal regulations (40 CFR Part 261 et seq) is dependent upon whether a material is a RCRA `listed hazardous waste`or has any of the four RCRA `hazardous waste characteristics.`Refer to 40 CFR Part 261.33 to determine if a given material to be disposed of is a RCRA `listed hazardous waste`; information contained in Section 15 of this MSDS is not intended to indicate if the product is a `listed hazardous waste.`RCRA Hazardous Waste Characteristics: There are four characteristics defined in 40 CFR Section 261.21-61.24: Ignitability, Corrosivity, Reactivity, and Toxicity. To determine Ignitability, see Section 9 of this MSDS (flash point). For Corrosivity, see Sections 9 and 14 (pH and DOT corrosivity). For Reactivity, see Section 10 (incompatible materials). For Toxicity, see Section 2 (composition). Federal regulations are subject to change. State and local requirements, which may differ from or be more stringent than the federal regulations, may also apply to the classification of the material if it is to be disposed. Cytec encourages the recycle, recovery and reuse of materials, where permitted, as an alternate to disposal as a waste. Cytec recommends that organic materials classified as RCRA hazardous wastes be disposed of by thermal treatment or incineration at EPA approved facilities. Cytec has provided the foregoing for information only; the person generating the waste is responsible for determining the waste classification and disposal method.

14. TRANSPORT INFORMATION

This section provides basic shipping classification information. Refer to appropriate transportation regulations for specific requirements.

US DOT

Proper Shipping Name: Not applicable/Not regulated
Hazardous Substances:
Not applicable

TRANSPORT CANADA

Proper Shipping Name: Not applicable/Not regulated

ICAO / IATA

Proper Shipping Name: Not applicable/Not regulated
Packing Instructions/Maximum Net Quantity Per Package:
Passenger Aircraft: -
Cargo Aircraft: -

IMO

Proper Shipping Name: Not applicable/Not regulated

15. REGULATORY INFORMATION

INVENTORY INFORMATION

United States (USA): All components of this product are included on the TSCA Chemical Inventory or are not required to be listed on the TSCA Chemical Inventory.

Canada: All components of this product are included on the Domestic Substances List (DSL) or are not required to be listed on the DSL.

European Union (EU): All components of this product are included on the European Inventory of Existing Chemical Substances (EINECS) or are not required to be listed on EINECS.

Australia: All components of this product are included in the Australian Inventory of Chemical Substances (AICS).

China: All components of this product are included on the Chinese inventory or are not required to be listed on the Chinese inventory.

Japan: All components of this product are included on the Japanese (ENCS) inventory or are not required to be listed on the Japanese inventory.

Korea: All components of this product are included on the Korean (ECL) inventory or are not required to be listed on the Korean inventory.

Philippines: All components of this product are included on the Philippine (PICCS) inventory or are not required to be listed on the Philippine inventory.

OTHER ENVIRONMENTAL INFORMATION

The following components of this product may be subject to reporting requirements pursuant to Section 313 of CERCLA (40 CFR 372), Section 12(b) of TSCA, or may be subject to release reporting requirements (40 CFR 307, 40 CFR 311, etc.) See Section 13 for information on waste classification and waste disposal of this product.

This product does not contain any components regulated under these sections of the EPA

PRODUCT HAZARD CLASSIFICATION UNDER SECTION 311 OF SARA

- Acute

16. OTHER INFORMATION

NFPA Hazard Rating (National Fire Protection Association)

Health: 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

Fire: 1 - Materials that must be preheated before ignition can occur.

Reactivity: 0 - Materials that in themselves are normally stable, even under fire exposure conditions.

Reasons For Issue: New Format

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